

In re application of:

CAI et al.

Appl. No.: 10/580,263

§ 371 Date: May 25, 2006

For: Derivatives of Gambogic Acid and Analogs as Activators of Caspases

and Inducers of Apoptosis

Confirmation No.: 2574

Art Unit: 1626

Examiner: (to be assigned)

Atty. Docket: 1735.0940001/RWE/BAH

## **Information Disclosure Statement**

Mail Stop Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents FP1-FP2 and NPL1-NPL48 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), no copies of U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application or before the mailing date of a first Office Action on the merits. No statement or fee is required.

Lu, G.B. et al., Yao Hsueh Hsueh Pao 19:636-639 (1984), Document NPL27, is in a foreign language. The relevance of Document NPL27 may be ascertained from the English-language abstract appearing at page 639 of that reference.

Qu, B.X. et al., Zhongguo Zhongliu Linchuang 18:50-52 (1991), Document NPL33, is in a foreign language. The relevance of Document NPL33 may be ascertained from the English-language abstract appearing at page 52 of that reference and from the English-language abstract provided herewith as Document NPL15.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond

Attorney for Applicants Registration No. 32,893

Date: 7/9/07

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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May 25 2006

Substitute for form 1449/PTO

## INFORM STATE

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(Use as many sheets as necessary)	Art Unit	1626
,	Examiner Name	(to be assigned)

**Application Number** 

\$ 271 Data

of Attorney Docket Number 1735.0940001/RWE/BAH Sheet

	*		U.S. PATENT DO	CUMENTS		
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines,	
Initials*	No. <sup>1</sup>	Number-Kind Code <sup>2 (If Known)</sup>	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	
	US1	3,989,816	11-02-1976	Rajadhyaksha, V.J.		
	US2	4,444,762	04-24-1984	Rajadhyaksha, V.J.		
	US3	6,462,041 B1	10-08-2002	Cai et al.		
	US4	6,335,429 B1	01-01-2002	Cai et al.		
	US5	6,613,762 B2	09-02-2003	Cai et al.		
	US6	7,176,234 B2	02-13-2007	Cai et al.		
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Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where	
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)			Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	FP1	WO 2000/044216 A2	08-03-2000	Cytovia, Inc.		
	FP2	WO 2004/002428 A2	01-08-2004	Cytovia, Inc.		
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Under the Paperwork Reduction is are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449/PTO Complete if Known Application Number 10/580,263 INFORMATION DISCLOSURE § 371 Date May 25, 2006 First Named Inventor Sui Xiong CAI STATEMENT BY APPLICANT Art Unit 1626 (Use as many sheets as necessary) Examiner Name (to be assigned) Sheet of Attorney Docket Number 1735.0940001/RWE/BAH

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL1	Adawadkar, P.D. et al., "Colouring Matters of Garcinia morella: Part VIII – Morellinol, Dihydromorelloflavone and Morelloflavone-7"-β-glucoside," Indian J. Chem. 14B:19-21, Council of Scientific & Industrial Research (1976)	
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	NPL4	Almond, J.B. and Cohen, G.M., "The proteasome: a novel target for cancer chemotherapy," <i>Leukemia 16</i> :433-443, Nature Publishing Group (April 2002)	i
	NPL5	Asano, J. et al., "Cytotoxic Xanthones from Garcinia hanburyI," Phytochem. 41:815-820, Elsevier Science Ltd. (1996)	
	NPL6	Batteux, F. et al., "Gene Therapy of Experimental Autoimmune Thyroiditis by In Vivo Administration of Plasmid DNA Coding for Fas Ligand," J. Immunol. 162:603-608, The American Association of Immunologists (1999)	
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	NPL8	Blanke, C.D., "Celecoxib With Chemotherapy in Colorectal Cancer,"  Oncology (Huntingt) 16(No. 4 Suppl. 3):17-21 (April 2002)	
	NPL9	Boirivant, M. et al., "Lamina Propria T Cells in Crohn's Disease and Other Gastrointestinal Inflammation Show Defective CD2 Pathway-Induced Apoptosis," Gastroenterology 116:557-565, American Gastroenterological Association (1999)	
	NPL10	Cao, SG. et al., "Novel Cytotoxic Polyprenylated Xanthonoids from Garcinia gaudichaudii (Guttiferae)," Tetrahedron 54:10915-10924, Elsevier Science Ltd. (1998)	

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				Application Number	10/580,263
INFORMAT	TION E	DISC	LOSURE	§ 371 Date	May 25, 2006
STATEMEN	STATEMENT BY APPLICANT		First Named Inventor	Sui Xiong CAI	
(Use	as many s	sheets a	s necessary)	Art Unit	1626
				Examiner Name	(to be assigned)
Sheet	2	of	5	Attorney Docket Number	1735.0940001/RWE/BAH

	,	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T²
	NPL11	Cao, SG. et al., "Cytotoxic Caged Tetraprenylated Xanthonoids from Garcinia gaudichaudii (Guttiferae)," Tetrahedron Lett. 39:3353-3356, Elsevier Science Ltd. (1998)	
	NPL12	Chinnaiyan, A.M. et al., "The inhibition of pro-apoptotic ICE-like proteases enhances HIV replication," Nat. Med. 3:333-337, Nature Publishing Company (1997)	
	NPL13	Coven, T.R. et al., "PUVA-induced lymphocyte apoptosis: Mechanism of action in psoriasis," <i>Photodermatol. Photoimmunol. Photomed.</i> 15:22-27, Blackwell Munksgaard (1999)	
	NPL14	Crawford, K.W. and Bowen, W.D., "Sigma-2 Receptor Agonists Activate a Novel Apoptotic Pathway and Potentiate Antineoplastic Drugs in Breast Tumor Cell Lines," Can. Res. 62:313-322, American Association for Cancer Research, Inc. (January 2002)	
	NPL15	Database Biosis, Accession No. PREV199191109495, Qu, BX. et al., "The Experimental Studies on Antineoplastic Action of Gambogic II," one page (1991)	
	NPL16	Giermasz, A. et al., "Potentiating Antitumor Effects of a Combination Therapy with Lovastatin and Butyrate in the Lewis Lung Carcinoma Model in Mice," Int. J. Cancer 97:746-750, Wiley-Liss, Inc. (February 2002)	
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	NPL20	Karanjgaonkar, C.G. et al., "Morellic, Isomorellic and Gambogic Acids," Tetrahedron Letts. 7:687-691, Pergamon Press Ltd. (1966)	

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				Application Number	10/580,263
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STATEM	STATEMENT BY APPLICANT		First Named Inventor	Sui Xiong CAI	
	(Use as many si	heets a.	necessary)	Art Unit	1626
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Sheet	3	of	5	Attorney Docket Number	1735.0940001/RWE/BAH

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL21	Kelland, L.R. et al., "Preclinical Antitumor Activity and Pharmacodynamic Studies with the Farnesyl Protein Transferase Inhibitor R115777 in Human Breast Cancer," Clin. Cancer Res. 7:3544-3550, American Association for Cancer Research, Inc. (2001)	
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	NPL23	Leong, YW. et al., "Forbesione, a Modified Xanthone from Garcinia forbesii," J. Chem. Res. (S):392-393, The Royal Society of Chemistry (1996)	
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	NPL25	Liu, W.M. et al., "The in vitro activity of the tyrosine kinase inhibitor ST1571 in BCR-ABL positive chronic myeloid leukaemia cells: synergistic interactions with anti-leukaemic agents," Br. J. Cancer 86:1472-1478, Nature Publishing Group (May 2002)	
	NPL26	López-Hoyos, M. et al., "Regulation of B cell apoptosis by Bcl-2 and Bcl-X <sub>L</sub> and its role in the development of autoimmune diseases (Review)," <i>Int. J. Mol. Med.</i> 1:475-483, D. A. Spandidos (1998)	:
	NPL27	Lu, G.B. et al., "Isolation and Structure of Neo-gambogic Acid from Gamboge (Garcinia hanburryi)," Yao Hsueh Hsueh Pao 19:636-639, The Chinese Pharmaceutical Association and The Institute of Materia Medica (1984)	
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	NPL29	Ohsako, S. and Elkon, K.B., "Apoptosis in the effector phase of autoimmune diabetes, multiple sclerosis and thyroiditis," <i>Cell Death Differ.</i> 6:13-21, Nature Publishing Group (1999)	
	NPL30	Ollis, W.D. et al., "The Constitution of Gambogic Acid," Tetrahedron 21:1453-1470, Pergamon Press Ltd. (1965)	

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Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Under the Paperwork Reduction Act of 1995, Substitute for form 1449/PTO Complete if Known 10/580,263 Application Number INFORMATION DISCLOSURE § 371 Date May 25, 2006 First Named Inventor Sui Xiong CAI STATEMENT BY APPLICANT Art Unit (Use as many sheets as necessary) 1626 Examiner Name (to be assigned) 4 of 1735.0940001/RWE/BAH Sheet 5 Attorney Docket Number

		NON PATENT LITERATURE DOCUMENTS	
Examiner Cite Initials* No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL31	O'Reilly, L.A. & Strasser, A., "Review: Apoptosis and autoimmune disease," <i>Inflamm. Res.</i> 48:5-21, Birkhäuser Verlag, Basel (1999)	
	NPL32	Ozawa, M. et al., "312-nanometer Ultraviolet B Light (Narrow-Band UVB) Induces Apoptosis of T Cells within Psoriatic Lesions," J. Exp. Med. 189:711-718, The Rockefeller University Press (1999)	
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	NPL37	Savill, J., "Apoptosis in resolution of inflammation," <i>J. Leukoc. Biol. 61</i> :375-380, Society for Leukocyte Biology (1997)	
	NPL38	Sgadari, C. et al., "HIV protease inhibitors are potent anti-angiogenic molecules and promote regression of Kaposi sarcoma," Nat. Med. 8:225-232, Nature America Inc. (March 2002)	
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	NPL41	Vaishnaw, A.K. et al., "The molecular basis for apoptotic defects in patients with CD95 (Fas/Apo-1) mutations," J. Clin. Invest. 103:355-363, The American Society for Clinical Investigation Inc. (1999)	!
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	NPL47	Zhou, T. et al., "Bisindolylmaleimide VIII facilitates Fas-mediated apoptosis and inhibits cell-mediated autoimmune diseases," Nat. Med. 5:42-48, Nature America Inc. (1999)	
	NPL48	Zou, C. et al., "Combined effect of chemopreventive agent N-(4-hydroxyphenyl) retinamide (4-HPR) and γ-radiation on bladder cancer cell lines," <i>Int. J. Oncol.</i> 13:1037-1041, D. A. Spandidos (1998)	
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	NPL50		

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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